K091013
Page 1 of 2

JUL 30 2009

## Section 5 – Traditional 510(k) Notification:- Summary

This Traditional 510(k) notification is to provide substantial equivalence for Advanced Medical Solutions Limited's Silver PU Antibacterial Foam Dressings, which are substantially equivalent to currently marketed devices intended for wound care.


**Submitted by:-** Advanced Medical Solutions Limited
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**Contact:-** Mrs Claire Ryan
Regulatory Affairs Manager
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**Date prepared:-** 3rd April 2009

**Common Name:-** Silver PU Antibacterial Foam Dressings

**Trade Names:-** Not yet defined

**Classification Name:-** Dressing, Wound, Drug

**Classification:-** Unclassified

**Product Code:-** FRO

**Legally marketed device(s) for substantial equivalence comparison:-**
Allevyn Ag Dressings, 510(k) # K063835, manufactured by Smith & Nephew.
Mepilex Ag Dressing, 510(k) # K071354 / K061554, manufactured by Mölnlycke Health Care.

**Device Description:-**
The Silver PU Antibacterial Foam Dressings is available in two variants:

Silver PU Antimicrobial Foam Dressing - Non-Adherent variant consists of a low friction waterproof polyurethane film, which also provides a bacterial barrier, laminated to hydrophilic absorbent polyurethane foam with a silver coated nylon mesh wound contact layer.

Silver PU Antimicrobial Foam Dressing – Island variant consists of a polyurethane waterproof membrane coated with pressure sensitive acrylic adhesive, which also provides a bacterial barrier, with a centrally located hydrophilic absorbent polyurethane foam with a silver coated nylon mesh wound contact layer.

Each Silver PU Antibacterial Foam Dressing contains a minimum of 0.26mg/cm$^2$ of elemental silver, the antibacterial action of the silver protects the dressing from bacterial contamination and provides an effective barrier to bacterial penetration.

The antibacterial properties of the dressing are effective for up to 7 days, as demonstrated in vitro, against a broad spectrum of microorganisms associated with wound infection, such as *Staphylococcus aureus,* including MRSA, *Staphylococcus epidermidis,* including MRSE, *Streptococcus pyogenes, Enterococcus faecalis (VRE)* and *Escherichia coli.* Silver Antibacterial Foam Dressings may reduce odour caused by micro-organisms in the wound. Odour reduction results from the antibacterial effect in the dressing.

Silver PU Antibacterial Foam Dressings are soft, highly absorbent, conformable and create the ideal environment for moist wound healing.

Silver PU Antibacterial Foam Dressings are suitable for use under compression bandaging.

Silver PU Antibacterial Foam Dressings are available in various sizes and shapes. The dressings are packaged in individual pouches, then into shelf cartons.

**Indications for use:**
Silver PU Antibacterial Foam Dressings are indicated for the management of light to moderate exuding partial and full thickness wounds, such as decubitus (pressure) ulcers, diabetic ulcers, leg ulcers, graft and donor sites, lacerations and abrasions, 1st and 2nd degree burns, trauma (dermal lesions, trauma injuries or incisions) and post-operative surgical wounds. Silver PU Antibacterial Foam Dressings are indicated for external use only.

**Manufacturing:-**
Silver PU Antibacterial Foam Dressings will be manufactured according to the product specification and under good manufacturing practices (GMP). A risk analysis has been performed in accordance with BS EN ISO 14971 to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

Advanced Medical Solutions Ltd, Silver PU Antibacterial Foam Dressings meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

**Testing:-**
Performance data for the Silver PU Antibacterial Foam Dressings have been established using antimicrobial, animal and bench testing. The biocompatibility of Advanced Medical Solutions Limited Silver PU Antibacterial Foam Dressings have been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1(Biological Evaluation of Medical Devices). Sterilisation validation has been performed in compliance with harmonised standards.

**Statement of Substantial Equivalence:-**
The indication for use, performance testing and antimicrobial activity for the Silver PU Antibacterial Foam Dressings are substantially equivalent to the predicate devices; Allevyn Ag Dressings, 510(k) # K063835, manufactured by Smith & Nephew and Mepilex Ag Dressing, 510(k) # K071354 / K061554, manufactured by Mölnlycke Health Care. The biocompatibility and performance testing for the Silver PU Antibacterial Foam Dressings have demonstrated that the device is safe and effective for the indications of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Medical Solutions Limited
% Ms. Claire Ryan
Road Three
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United Kingdom

JUL 30 2009

Re: K091013
Trade/Device Name: Silver PU Antibacterial Foam Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 17, 2009
Received: July 22, 2009

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K091013

Device Name: **Silver PU Antibacterial Foam Dressings**

Indications for Use:

Silver PU Antibacterial Foam Dressings are indicated for the management of light to moderate exuding partial and full thickness wounds, such as:

- Decubitus (pressure) ulcers
- Diabetic ulcers
- Leg ulcers
- Graft and donor sites
- Lacerations and abrasions
- 1st and 2nd degree burns
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- Post-operative surgical wounds

The Silver PU Antibacterial Foam Dressings are indicated for external use only

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091013